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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,021	08/06/2001	Yongming Sun	DEX-0150	7327
26259	7590	10/23/2003	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			UNGAR, SUSAN NMN	
			ART UNIT	PAPER NUMBER
			1642	
			DATE MAILED: 10/23/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/762,021

Applicant(s)
Sun et al

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 15, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1642

1. The Amendment filed September 15, 2003 (Paper No. 17) in response to the Office Action of August 15, 2003 (Paper No. 16) is acknowledged and has been entered. Previously pending claim 1 has been amended. Claim 1 is currently being examined.

It is noted that a review of Paper No. 15, filed June 10, 2003, reveals that the response is drawn to the previously withdrawn invention, that is the diagnosis of colon cancer comprising assaying SEQ ID NO:1 and is therefore is not relevant to the instantly claimed invention.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are maintained:

Claim Rejections - 35 USC § 112

4. Claim 1 remains rejected under 35 USC 112, first paragraph, for the reasons previously set forth in Paper No. 14, Section 5, pages 4-8.

Applicant states that the amendment of the claim to recite a protein expressed by SEQ ID NO:1 draws the claimed invention back to the invention elected in the response to the Restriction requirement filed December 13, 2002. The argument has been considered and has been found persuasive and the withdrawal of claim 1 from further consideration is hereby withdrawn.

Applicant further states that the foregoing comprises a full and complete response to the Office communication of record. However, it is noted that Applicant has not traversed any of the rejections drawn to diagnosis of colon cancer comprising assaying a CSG protein or a protein expressed by SEQ ID NO:1.

Art Unit: 1642

Because Applicant has not distinctly and specifically point out the supposed errors in the rejection under 35 USC 112, first paragraph drawn to diagnosis of colon cancer comprising assaying a protein, or assaying a protein expressed by SEQ ID NO:1, the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. Claim 1 is under 35 USC 102(a) and 35 USC 102(e) essentially for the reasons previously set forth in Paper No. 14, Section 7, pages 9-10 and further for the reasons set forth below.

The claim is drawn to a method for diagnosing the presence of colon cancer comprising measuring levels of CSG protein encoded by SEQ ID NO:1 in cells, tissues or bodily fluids in a patient and comparing the measured levels with levels of CSG encoded by SEQ ID NO:1 in cells, tissues or bodily fluids from a normal control.

US Patent No. 5,733,748 teaches as set forth previously that is, US Patent No. 5,733,748 teaches a method of utilizing Human Colon Specific Gene (CSG) polypeptides as a diagnostic marker for colon cancer (see abstract) wherein the diagnosis is by detecting altered levels of CSG polypeptides in a biological sample, tissue, elevated levels of CSG polypeptides, wherein the assays are well known in the art, wherein the tissue can be biological fluids, cell samples diagnosing colon cancer comprising measuring levels of CSG polypeptides (col 9, line 52-col 4, line 3). Although the reference does not specifically teach that the levels of CSG polypeptides are elevated above normal controls, it would be reasonable to conclude

Art Unit: 1642

and one of skill in the art would instantaneously know that the elevated levels are levels elevated above a normal control. Further, although the reference does not specifically teach that the CSG protein is expressed by SEQ ID NO:1, the claimed method appears to be the same as the prior art method, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product assayed in the prior art does not possess the same material, structural and functional characteristics of the product assayed in the instantly claimed invention. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method of assaying CSG protein expressed by SEQ ID NO:1 is different from that taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

6. All other objections and rejections recited in Paper No. 14 are hereby withdrawn.

7. No claim allowed.

8. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R.

§ 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE

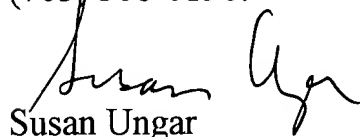
Art Unit: 1642

ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Susan Ungar
Primary Patent Examiner
October 22, 2003